PLEASE GIVE 1 BOOKLET TO THE PATIENT, FILE 1 IN THE PATIENT MEDICAL NOTES AND ATTACH 1 TO A COPY OF THE CONSENT FORM FOR THE PATIENT PACK.

[traditional patient information leaflet. Version 3.1, 02/02/2016; this text to be removed prior to use]

NHS TRUST LOGO

FOCUS Patient information sheet (traditional format) Version 3.1 02/02/2016

1. Study Title

Fluoxetine Or Control Under Supervision (FOCUS) – a study to establish whether fluoxetine improves recovery after stroke.

2. Invitation paragraph

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish e.g. your relatives or other health care professionals.

- Part 1 of this information sheet tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detail about how the study is run.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

3. What is the purpose of this study?

Strokes can cause weakness of arms and legs, problems with speech, eyesight and even with memory, concentration and fatigue. Although these problems often improve after a stroke, many people will have long-term problems.

The FOCUS study aims to find out whether a drug called Fluoxetine improves patients' recovery so that they have fewer long-term problems. Fluoxetine is manufactured by several different companies which use their own trade names e.g. Prozac, Sarafem.

Fluoxetine has been used for many years to treat people with depression. However, small studies have suggested that it might also improve recovery after stroke by helping the brain repair itself.

We want to find out whether patients given one fluoxetine capsule each day for six months after a stroke recover better than those given a placebo (or dummy) capsule. This study will recruit at least 3000 patients in stroke units and clinics from all over the UK. If effective, fluoxetine could become part of routine stroke care.

4. Why have I been invited to take part?

You have been invited to take part because you recently had a stroke and currently have some ongoing stroke-related problems.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to stop taking the study capsules if you wish, or to withdraw completely from the study at any time and without giving a reason. A decision to withdraw or not to take part will not affect the care you receive.

6. What will happen to me if I take part?

A member of the research team will collect some information about your medical condition from your notes, ask you some simple questions, record your home address and telephone numbers, and those of your next of kin or other close personal contacts, so that the study team can contact you later to find out how you are doing. The research team will enter this information into a computer, which will then randomly allocate you to take either fluoxetine, or a 'dummy' capsule. Half the patients in the study will receive the 'dummy' capsule and half will receive the fluoxetine capsule.

The two capsules look identical, so neither you, nor your doctors or nurses, will know whether you are receiving the fluoxetine capsule or the dummy capsule. You will be asked to take the capsule once a day for 6 months. If you cannot swallow the capsules and have a feeding tube, the contents of the capsule will be put down your tube. Fluoxetine has few side effects. Most of these are not serious. Part 2 describes them. If you develop any symptoms which you think might be due to the capsules, you should inform the doctors or nurses responsible for your care.

<u>First follow-up assessment</u>

When you leave the stroke unit or move to a rehabilitation unit, information about how you are will be collected from your medical notes.

If you required only out-patient treatment for your stroke, the trial office will contact you and your general practitioner at one month to find out whether you are still taking the trial medication, whether you have had any side effects, and whether you have been started on any other medication

We will write to you at three months to provide you with an opportunity to tell us how things are going, whether you are taking the trial capsules, and whether you have had any side effects.

Assessment at 6 months after your stroke
We will contact your general practitioner (GP) to find if you are still taking the capsules, whether you have had any side effects and whether you have been started on any other medications. The trial team will write to you, and ask you to complete a questionnaire about how you have been getting on since your stroke. You will return the completed questionnaire in a freepost envelope or enter this information on line via a personal computer linked to the internet. If we don't hear from you, one of our research team in Edinburgh will contact you by telephone. If we cannot contact you we will contact your next of kin.

After the 6-month assessment, the study capsules will be stopped. You will return the bottles, and any unused capsules to us. You may do this by post or by sending it back to your local hospital. Postal costs will be covered by the study.

Assessment at 12 months after your stroke.
We will check with your GP and then contact you again by post or telephone. We will ask you to complete the same questionnaire as you completed at 6 months. This will allow us to find out whether any benefit from the fluoxetine continues after it has been stopped.

7. What happens after the 12-month assessment?
After the 12-month assessment, we will not contact you again. In the longer term, we would like to know how you are doing. The Health and Social Care Information Centre and other National Health Service bodies in the UK holds health information, such as hospital admissions, and we would like to use this routinely collected health data to tell us how you are doing.

8. What are the possible benefits of taking part?

If you are prescribed the fluoxetine, and the study shows that it improves recovery after stroke, you may have benefited directly from taking part.

Some patients find it helpful to be part of a research study and be under regular follow-up.

The results of the study will help us to treat future patients with stroke better.

9. What are the possible disadvantages and risks of taking part?

Apart from the possible inconvenience of the researcher taking up some of your time, we do not envisage any particular risks from your taking part. There are sometimes side effects from fluoxetine, but these are uncommon and are generally mild (see part 2). If any of your doctors think you would benefit from an antidepressant whilst you are in the study they will be able to use one that is compatible with the study medication.

10. What happens when the study stops?
We would like to provide you with regular updates on how the study is going, including the final results of the study. If you wish to receive these you can provide us with an email address (your own, or that of somebody close to you) or a postal address. We will also put the trial results on our trial website.

11. **What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Part 2 describe this in detail.

12. **Will my taking part in the study be kept confidential?**

Yes. All personal information will be kept confidential (see part 2).

13. Contact Details:

For further information, please contact Professor Dennis, who are leading the study via the FOCUS 24 hour helpline 0131 242 7741
If you have any concerns about the study, please contact Professor Dennis in the first instance.

This completes Part 1 of the Information Sheet.
If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part 2

14. What if relevant new information becomes available?

If new information becomes available which might influence whether you should continue to take part in the study, we will contact you.

15. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time. However, if you do decide to withdraw, we would like to keep the information we have already collected about you.

If during the course of the study you become less well so that that you can no longer give consent, we would still like to keep you in the study.

If you stop taking the study capsules, we would still like to keep you in the study and follow you up.

16. What if there is a problem?

If you have a complaint about your treatment by members of staff (doctors, nurses etc), you should complain through the usual NHS complaints system.

If you have a complaint about the FOCUS study, you should contact Professor Professor Dennis via the 24 hour FOCUS trial helpline. The number is 0131 242 7741 If a serious adverse event occurs, it will be reported to the sponsor of the study (NHS Lothian and University of Edinburgh).

17. **Will my taking part in this study be kept confidential?**

Our procedures for handling, sharing, processing, storage and destruction of medical data are compliant with the Data Protection Act 1998.

We will obtain your permission to access your medical records and to collect data about you from The Health and Social Care Information Centre and other central UK NHS bodies during the course of the study and in the longer term.

Data about you will be stored on a secure computer database. The research team will be authorized to have access to the information.

The sponsors of the research (University of Edinburgh and NHS Lothian), and regulatory authorities will have access, as necessary, to view the information for monitoring the quality of research. All have a duty of confidentiality to you as a research participant.

You have the right to check the accuracy of information held about you and correct any errors.

18. Involvement of the General Practitioner/Family doctor (GP)

Your own general practitioner will be informed about your taking part in the study. Your general practitioner will be asked to report to the trial team any adverse effects that you experience as a result of participating in the trial.

19. Will any blood, genetic tests or X Rays be done as part of the study?

No, the study does not involve any extra tests.

20. What will happen to the results of the research study?

The results of the study will be published in medical journals. We will also send a report to the funders of the study. No individual patient will be identified in these reports.

21. **Who is organising and funding the research?**

The University of Edinburgh and NHS Lothian are co-sponsors of the research and are overseeing it. Professor Martin Dennis and Professor Gillian Mead are in charge of the study. They are not being paid for including you. The Stroke Association and Health Technology Assessment is funding the study.

22. **Who has reviewed the study?**

The Scottish Multicentre Research Ethics Committee has approved this study for conduct in the NHS (or private sector).

23. **What are the possible adverse reactions to fluoxetine?**

Fluoxetine has been extensively tested in clinical trials in patients with depression. It has been shown to be reasonably safe and well tolerated over many years.

It has been widely used to treat mood disorders in stroke survivors. In previous stroke studies indigestion, loss of appetite and sleep disturbance has been more common amongst those taking fluoxetine than placebo medication.

Over the page, we have listed all the side effects that have ever been noted. Everyone's reaction to a medicine is different. It is difficult to predict which, if any, side-effects you will have from taking a particular medicine.

The list of side-effects looks worrying. A small number are serious but the majority cause only minor inconvenience and will wear off over a couple of weeks as your body gets used to the medication. If the medication is stopped, the side effects will also wear off. It is important to have this whole list, though, so you can recognise side-effects if they happen.

If you do suffer symptoms that you think might be related to the trial medication, please mention this to your hospital doctor (if you are still an inpatient) or to your general practitioner, or contact the trial team.

A**ll the side effects of fluoxetine that have ever been noted**

The following side effects have been described, but their frequency is unknown.

- drop in blood pressure on standing or sitting up
- abnormal muscle movements such as twitches, tremors or jerks; balance or coordination problems; bruising and other bleeding problems
- blurred vision or eyesight problems
- feeling anxious, nervous or agitated; panic attacks, dizziness, drowsiness, tiredness, sleepiness, yawning, restlessness and inability to sit still, hallucinations, abnormal dreams, concentration problems; confusion, depersonalisation or unusual thoughts, euphoria, mania or mania-like behaviour
- dry mouth, loss of appetite, weight loss, nausea, vomiting, indigestion, swallowing difficulties or bad taste in the mouth, diarrhoea
- hypersensitivity or allergic reactions – swelling of the face or tongue, or anaphylactic reaction
- skin rashes: urticaria, itching, ulceration of the mouth, sore throat, hair loss, light sensitivity
- chills, sweating, production of breast milk
- not being able to pass urine or urinating more often
- abnormal laboratory test results, liver problems, breathing difficulties, lung problems, metabolic problems, blood sugar control changes in diabetics
- headaches, joint pain, bone fractures, muscle pain or tenderness
- seizures
- abnormally high body temperature, rigidity, muscle twitches or sudden jerks, mental changes including confusion, irritability, agitation, delirium or coma. These symptoms in combination might suggest a very rare complication called the serotonin or neuroleptic malignant-type syndrome - this may be fatal. You or your carer must seek immediate medical help if you get these symptoms
- sexual dysfunction including delayed or absent ejaculation or difficulty achieving an orgasm
- thoughts of committing suicide or suicidal tendencies – the risk of this is extremely low. It is slightly more common in depressed adolescents than in older people with depression
- withdrawal symptoms can occur when this medicine is stopped abruptly. These include dizziness, sensory changes such as tingling feelings, weakness, increased agitation, anxiety, sleeping problems including sleep disturbances or intense dreams, nausea, vomiting, tremors or headaches.